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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,657	04/18/2005	Karina Drumm	129402.00201	9864

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EXAMINER
WOLLENBERGER, LOUIS V

ART UNIT	PAPER NUMBER
1635	

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DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,657	DRUMM ET AL.	
	Examiner	Art Unit	
	Louis V. Wollenberger	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *2* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 3-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Election/Restriction

Applicant's election with traverse of Group I, claims 1 and 3, in the reply filed on 3/17/2006 is acknowledged. Also acknowledged are Applicants' amendments to the claims, canceling claims 24-91, withdrawing claim 2, and amending claims 3–23.

Accordingly, claims 1-23 are pending. Claim 2 has been withdrawn by applicants, and is considered by the examiner to be drawn to a non-elected invention, as explained in the previous Requirement.

Applicants' traversal, directed to claims 4-23, is premature because claims 4-23 have never been subjected to restriction because of their improper multiple dependent form.

Thus, Applicants' traversal is moot.

However, with the amendment filed on 3/17/2006, Applicants have corrected the dependencies of claims 4-23 and placed the claims in condition for examination.

Accordingly, Applicants' amendments have necessitated the following supplemental Restriction Requirement.

Claims 1 and 3-23 are subject to Restriction as follows.

Supplemental Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 3-13, 17-23 drawn to drawn to a method for the treatment of a disorder of the central nervous system and/or eye, comprising the administration of a compound capable of modulating a target gene or gene product, **wherein the compound may be a nucleic acid molecule, and more particularly, an antisense nucleic acid or a ribozyme**. Election of this group requires the further election of a single nucleic acid **or** amino acid sequence, SEQ ID NO:1, 2, 3, or 4, recited in claim 19, as explained below.

Group II, claim(s) 1, 3-13, 17-23 drawn to drawn to a method for the treatment of a disorder of the central nervous system and/or eye, comprising the administration of a compound capable of modulating a target gene or gene product, **wherein the compound may be a nucleic acid molecule, and more particularly, a sense nucleic acid molecule**. Election of this group requires the further election of a single nucleic acid **or** amino acid sequence, SEQ ID NO:1, 2, 3, or 4, recited in claim 19, as explained below.

Group III, claim(s) 1, 3-11, 13, 14-16, 19-23 drawn to drawn to a method for the treatment of a disorder of the central nervous system and/or eye, comprising the administration of a compound capable of modulating a target gene or gene product, **wherein the compound may be a nucleic acid molecule, and more particularly, a dsRNA**. Election of this group requires the further election of a single nucleic acid **or** amino acid sequence, SEQ ID NO:1, 2, 3, or 4, recited in claim 19, as explained below.

Group IV, claim(s) 1, 3-11, 19-23 drawn to drawn to a method for the treatment of a disorder of the central nervous system and/or eye, comprising the administration of a compound capable of modulating a target gene or gene product, **wherein the compound may be a polypeptide**. Election of this group requires the further election of a single nucleic acid **or** amino acid sequence, SEQ ID NO:1, 2, 3, or 4, recited in claim 19, as explained below.

Group V, claim(s) 1, 3-11, 19-23 drawn to drawn to a method for the treatment of a disorder of the central nervous system and/or eye, comprising the administration of a compound capable of modulating a target gene or gene product, **wherein the compound may be an antibody**. Election of this group requires the further election of a single nucleic acid **or** amino acid sequence, SEQ ID NO:1, 2, 3, or 4, recited in claim 19, as explained below.

Group VI, claim(s) 1, 3-11, 19-23 drawn to drawn to a method for the treatment of a disorder of the central nervous system and/or eye, comprising the administration of a compound capable of modulating a target gene or gene product, **wherein the compound may be a ligand binding molecule**. Election of this group requires the further election of a single nucleic acid **or** amino acid sequence, SEQ ID NO:1, 2, 3, or 4, recited in claim 19, as explained below.

The inventions listed as Groups I–VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The subject matter common to Groups I–VI is a compound capable of modulating a target gene or gene product. However, this cannot be the special technical feature because the element is shown in the prior art. Elbashir et al. (2001) *Nature* 411:494–498 (cited in the previous Requirement) teach an siRNA duplex that suppresses the expression of *Photinus pyralis* luciferase in several different mammalian cell lines (Figs. 1 and 2, page 495), and an siRNA duplex that suppresses lamin A/C in cultured HeLa cells (Fig. 4, page 497).

Thus, unity of invention is lacking, *a posteori*, on that basis.

The special technical features of Groups I, II, and III are, in turn, a ribozyme or antisense nucleic acid molecule, a sense nucleic acid molecule, and a dsRNA (e.g., an siRNA) capable of inhibiting the expression of a target gene. These features are not shared among groups I–III or present in any of groups IV, V, or VI. The special technical feature of Groups IV, V, and VI are, in turn, a polypeptide, an antibody, and a ligand binding molecule capable of inhibiting the activity of a gene product. These features are not shared among Groups IV–VI or present in any of groups I, II, or III.

Thus, unity of invention is lacking *a priori*, as the groups lack the same or corresponding special technical feature.

Restriction to a Single Nucleotide Sequence

Claim 19 recites a Markush grouping of four different sequences identified as SEQ ID Nos: 1–4.

Claim 19 specifically claims four different methods for modulating the expression or activity of four different nucleic acid and amino acid sequences, comprising a sequence selected from any one of the SEQ ID NOS: 1–4.

The nucleic acid and amino acid sequences listed in Claim 19 do not relate to a single general inventive concept because, according to the guidelines set forth in MPEP §1850, they lack the same or corresponding special technical features for the following reasons:

According to the guidelines in MPEP §1850, Section III.B., the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, which applies to National Stage Applications, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B)

(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B)

(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

In paragraph (B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

In the instant case, several alternative nucleic acid SEQ ID NOs are recited in the instant claims. The alternative sequences do not appear to share a significant structural element, according to the criteria above, wherein each member could be substituted for the other with the expectation that the same result would be achieved.

Each sequence appears to be structurally unique, and may therefore be expected to have different properties in the context of the invention as a whole. Thus, each member of the class cannot be substituted, one for the other, with the expectation that modulation of each will produce the same effect.

Further, although the instant sequences may share a common utility and/or function, the sequences do not meet the criteria of (B)(1), as they do not appear to share, one with another, a common structure.

Accordingly, unity of invention between the sequences of the instant application is lacking and each sequence claimed is considered to constitute a special technical feature.

Thus, Applicants are required to elect a single sequence, either SEQ ID NO:1, 2, 3, or 4, for prosecution with the elected Group.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on Mon–Fri, 8:00 am–4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval system (PAIR). Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Examiner
Art Unit 1635
April 13, 2006

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